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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,759	05/30/2001	David S. Terman		8812

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,759	TERMAN, DAVID S.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-6,11-25,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-10, 26, 29 and 30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of group IV on November 4, 2004 is acknowledged. However, upon reconsideration the elected claims appear to be drawn to more than one invention.

Claims 1-30 are pending.

Claims 1-6, 11-25, 27, and 28, drawn to non-elected inventions, are withdrawn from consideration.

Claims 7-10, 26, 29 and 30 are restricted to the following groups of inventions.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7 and 26, drawn to methods for producing tumoricidal immunocytes or T cells populations in vivo, classified in class 514, subclass 558.

II. Claims 8-10, drawn to methods of treatment using tumoricidal immunocytes, T cells or antigen presenting cells that have been produced ex vivo, classified in class 424, subclass 93.71.

III. Claim 29, drawn to method for producing tumoricidal T cell population comprising contacting T cells with a superantigen-lipid raft conjugate, classified in class 435, subclass 372.3 and class 424, subclass 278.1.

IV. Claim 30, drawn to method of treatment using tumoricidal T cells that have been contacted with a superantigen-lipid raft conjugate, classified in class 424, subclass 93.71.

The inventions are distinct, each from the other, for the following reasons:

Each of the invention groups is drawn to a different method requiring different steps and resulting in different outcomes. In the method of group I, the methods appear to require that a mammal be administered either one of a set of antigens selected from the group immunosuppressive fatty acids, ceramides, glycolipids, sphingolipids, glyosphingolipids, phosphosphingolipids, gangliosides, sialylated glycans, lipopepetides, or proteglycolipids; or with a tumor associated antigen, where one of these compounds will contact an immunocyte or a T cell to produce a tumoricidal immunocyte population or a tumoricidal T cell. In contrast, the methods of treatment of groups II require a step of ex vivo contact between tumor associated lipids an either an immunocyte, an antigen presenting cell or a T cell and then a step of administering the resultant immunocyte, antigen presenting cell of T cell to a mammal. Therefore, the steps of the two groups are different and the outcomes of the two methods are different, because one method results in the making of a tumoricidal population of cells and the other results in the treatment of a mammal. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

The invention of group III is different from either of the inventions of group I or group II, because the claimed methods require the step of contacting T cells with a superantigen-lipid raft conjugate, which is a different compound from the set of antigens selected from the group: immunosuppressive fatty acids, ceramides, glycolipids, sphingolipids, glyosphingolipids, phosphosphingolipids, gangliosides, sialylated glycans, lipopepetides, or proteglycolipids; or a tumor associated antigen. Also, the end-point of the method of group III is different from that of

the methods of group II, because the end-point of the methods of group III is to produce a tumoricidal T cell, whereas the endpoint of the methods of group II is to treat a mammal. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper.

The invention of group IV is different from any of the inventions of group III, II or I. In the case of the inventions IV and III, the two inventions differ in method end-point, where the invention of group IV is for the treatment of a mammal, whereas the end-point of group III is for the production of a tumoricidal T cell. In the case of inventions IV and II, the method differ because different products are used. Group IV requires the ex vivo incubation of T cells with a superantigen-lipid raft conjugate, whereas, group II requires ex vivo incubation of either immunocytes, antigen presenting cells or T cells with tumor associated lipids. In the case of inventions IV and I, the method steps differ because different products are used and because different methods steps are required for the operation of the claimed methods to achieve the different outcomes. In the case of group IV, the steps require the use of a superantigen-lipid raft conjugate to contact T cells ex vivo, where these cells are then used to treat a mammal, whereas in group I, the steps require the administration either, one antigen from a set of antigens selected from the group immunosuppressive fatty acids, ceramides, glycolipids, sphingolipids, glyosphingolipids, phosphosphingolipids, gangliosides, sialylated glycans, lipopepetides, or proteglycolipids; or a tumor associated antigen, where the contacting with the immunocyte or T cell is in vivo, and the end-point of the method is the production of tumricidal immunocytes or

tumoricidal T cells.Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group IV, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group IV, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper.

3. If invention group I is elected, then a further election of species is required to start the examination process of this group. Claims 7 and 26 are generic to a plurality of disclosed patentably distinct species comprising a set of compounds selected from the group immunosuppressive fatty acids, ceramides, glycolipids, sphingolipids, glyosphingolipids, phosphosphingolipids, gangliosides, sialylated glycans, lipopepetides, or proteglycolipids; or tumor associated antigen. The specification on pages 94-102 appears to disclose a number of tumor associated lipids/antigens and receptors that might be deactivated of deleted in the claimed methods. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of tumor associated lipid/antigen and receptor or adaptor protein that will be deleted or inactivated, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
March 7, 2005

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER